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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,422	10/22/2007	John L. Telford	002441.00189	9353

27476 7590 11/10/2009

NOVARTIS VACCINES AND DIAGNOSTICS INC.
INTELLECTUAL PROPERTY- X100B
P.O. BOX 8097
Emeryville, CA 94662-8097

EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	**PAPER NUMBER**
1645	

MAIL DATE	DELIVERY MODE
11/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,422	TELFORD ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22-30* is/are pending in the application.

4a) Of the above claim(s) *5-7,11-13,18-20 and 22-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8-10,14-17 and 27-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/17/08, 05/01/09, 05/04/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

1) Acknowledgment is made of Applicants' preliminary amendments filed 10/22/07, 05/04/09 and 08/17/09.

Election

2) Acknowledgment is made of Applicants' election filed 05/04/09, with traverse, in response to the lack of unity mailed 11/06/08.

Applicants have elected invention I, claims 1-17, and the GBS fragment species, SEQ ID NO: 7, and the bivalent combination species of GBS80, SEQ ID NO: 7 and GBS322 species. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

Status of Claims

3) Claim 8 has been amended via the amendment filed 10/22/07.

Claim 21 has been canceled via the amendment filed 10/22/07.

Claims 1, 8-17, 19 and 20 have been amended via the amendment filed 08/17/09.

New claims 22-30 have been added via the amendment filed 08/17/09.

Claims 1-20 and 22-30 are pending.

Claims 5-7, 11-13, 18-20 and 22-26 are withdrawn from consideration as being directed to non-elected invention or species. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 1-4, 8-10, 14-17 and 27-30 are under examination. A First Action on the Merits on these claims is issued.

Sequence Listing

4) Acknowledgment is made of Applicants' submission of the sequence listing which have been entered on 11/06/07.

Information Disclosure Statements

5) Acknowledgment is made of Applicants' Information Disclosure Statements filed 04/17/08, 05/01/09 and 5/04/09. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Priority

6) The instant application is the national stage 371 application of the international application, PCT/US2004/030032, filed 09/15/04 and claims priority to the provisional application 60/548,789 filed 02/26/04 and to PCT/US2003/029167 filed 09/15/2003.

Objection(s) to Specification

7) The specification is objected to for the following reasons:

(a) The use of the trademarks has been noted in this application. For example, see line 22 on page 57 and lines 11 and 15 of page 62 of the specification for 'Tween 80'; line 22 on page 57 for 'Span 85'; and line 13 on page 58 and line 11 of page for 'pluronic'. The trademark recitation should be capitalized. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification and make necessary changes wherever trademark recitations appear.

(b) The amino acid sequence LPXTG depicted at line 17 of page 48 and the GSGGGG sequence recited at line 29 of page 50 of the specification are longer than four amino acids in length. Yet the sequence is not identified by a specific SEQ ID number as required under 37 C.F.R 1.821 through 1.825. Any sequences recited in the instant specification, which are encompassed by the definitions for nucleotide and/or amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) must comply with the requirements of 37 C.F.R 1.821 through 1.825. Note that branched sequences are specifically excluded from this definition.

APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R 1.821(g).

Rejection(s) under 35 U.S.C § 101

8) 35 U.S.C. § 101 states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this cycle.

9) Claims 1, 14 and 27 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1, 14 and 27, as written, do not sufficiently distinguish over a GBS V bacterium comprising GBS 80 or a fragment thereof; SEQ ID NO: 7 and a sip; and a fusion protein comprising a portion of SEQ ID NO: 3 and at least a portion of one other GBS antigen as they exist naturally on the surface of the bacterium, because the claims do not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring product. Note that a dipeptide from SEQ ID NO: 3 and a dipeptide from one other GBS polypeptide antigen constitute 'a portion'; therefore a dipeptide from each antigen fused directly or indirectly and as present naturally on the surface of a bacterium read on the claim. The recited antigens are not 'isolated' or 'purified' antigens and therefore read on one or more polypeptide antigens, portions thereof or fusion proteins thereof as present of whole cells of GBS type V bacteria. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980)*. The claim(s) should be amended to indicate the hand of the inventor, e.g., by insertion of --a purified--, --an isolated--, or --an isolated and purified-- if descriptive support exists for such a limitation in the instant specification. See MPEP 2105.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

10) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

11) Claims 1-4, 8-10, 14-17 and 27-30 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant(s) regards as the invention.

(a) Claims 1-4, 8-10, 14-17 and 27 are vague and indefinite in the abbreviated limitation: 'GBS', because it is unclear what does this limitation encompass. It is suggested that the abbreviation be recited as a full terminology at first occurrence in the base claim, with its abbreviated recitation retained therein in parentheses.

(b) Claims 1, 10, 14-17 and 27 are vague and indefinite in the limitation 'as represented by' because it is unclear whether it represents open or closed claim language. For the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the above-identified limitation with the limitation --set forth as--.

(c) Claim 2 is indefinite in the limitation: 'improved immunogenicity'. The limitation 'improved' is a relative term which renders the claim indefinite. The term 'improved' is not specifically defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and therefore, one of ordinary skill in the art would not be reasonably appraised of the scope of the claim.

(d) Claim 1 is indefinite in the limitation 'fragment', because it is unclear what is encompassed in this limitation. What constitutes a 'fragment', and how much of the polypeptide's original structure has to be retained such that the resulting polypeptide can be considered a 'fragment' is not clear. The metes and bounds of the structure encompassed in the limitation 'fragment' are indeterminate. Does a single amino acid constitute a 'fragment'?

(e) Analogous rejection and criticism apply to claim 14 with regard to the limitation: 'a portion'.

(f) Claim 2 is indefinite because it lacks proper antecedence in the limitation 'GBS antigens' (see line 1). Claim 2 depends from claim 1, which already includes the limitation 'GBS antigens'. For proper antecedent basis, it is suggested that Applicants replace the above-identified limitation with the limitation --the GBS antigens--.

(g) Claim 2 is indefinite because it has improper antecedent basis in the limitation 'the Active Maternal Immunization Assay' (see line 2). There is no earlier recitation of Active Maternal Immunization Assay in the claim or in the claim from which it depends.

(h) Claim 2 is indefinite in the limitation: 'serum titers … during an immunization schedule and percent survival rate of pups after challenge', because it is unclear serum titers of which element having what immunospecificity is measured. What does the recited

'immunization schedule' comprise is not cleat. Are the pups of rats, mice, or other animals? What are the pups challenged with? The metes and bounds of the claim are indeterminate.

(i) Claim 8 is indefinite because it lacks proper antecedence in the limitation 'GBS 80' (see line 1). Claim 8 depends from claim 1, which already includes the limitation 'GBS 80'. For proper antecedent basis, it is suggested that Applicants replace the above-identified limitation with the limitation --the GBS 80--.

(j) Claim 15 is indefinite because it has antecedence issue with 'said at least one GBS antigen'. Claim 15 depends from claim 14, which recites 'at least one different GBS antigen', but not at least one GBS antigen. For proper antecedent basis, it is suggested that Applicants replace the above-identified limitation with the limitation -- said at least one different GBS antigen --.

(k) Analogous rejection and criticism apply to claim 16 with regard to the limitation: 'said at least one GBS antigen'.

(l) Claim 17 is indefinite because it lacks proper antecedent basis in the limitations: 'a GBS 80 antigen as represented by SEQ ID NO:3' and ' GBS 322 antigen as represented by SEQ ID NO:38'. Claim 17 depends from claim 16 and indirectly from claim 14, which already include such limitations. It is suggested that Applicants provide proper antecedence to each limitation.

(m) Claim 28 is vague and indefinite in the limitation 'surface immunogenic protein (sip)' because it is unclear what it represents or what is encompassed in this limitation. Is it a eukaryotic protein? The structure, size, length, and/or the source of 'surface immunogenic protein (sip)' is not clear.

(n) Claim 29 is vague in the limitation: 'amino acid sequence SEQ ID NO:3'. For the purpose of distinctly claiming the invention, it is suggested that Applicants replace the above-identified limitation with the limitation --amino acid sequence of SEQ ID NO: 3--.

(o) Claims 2-4, 8-10, 15-17, 29 and 30, which depend directly or indirectly from claim 1, 14 and 28 respectively, are also rejected as being indefinite because of the indefiniteness identified above in the base claims.

Rejection(s) under 35 U.S.C § 102

12) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> **(e)** the invention was described in-
> **(1)** an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language.

13) Claims 1-4, 8-10, 14-17 and 27-30 are rejected under 35 U.S.C. § 102(e)(1) as being anticipated by Tettelin *et al.* (WO 2004/018646 A2 – Applicants' IDS).

Tettelin *et al.* taught an immunogenic composition comprising two or more GBS polypeptides or fragments thereof, or a fusion protein thereof. One combination composition consists of two GBS polypeptides or fragments thereof. The composition comprises an adjuvant and induces a protective immune response particularly in a human. See claims 1-9; last paragraph on pages 10, 21; fourth full paragraph on page 11; pages 13 and 14; third full paragraph on page 22; 'Vaccines and Immunisation' beginning on page 23; pages 29-33 including the first and fitth full paragraphs of page 32; and 'Pharmaceutical Compositions' and 'Vaccines' on pages 63-65 and 70. The amino acid sequences of the prior art have 100% sequence identity with the instantly recited amino acid sequences of SEQ ID NO: 3, SEQ ID NO: 38 and SEQ ID NO: 7 respectively. See the sequence alignments below.

SEQ ID NO: 3

```
ADL00034
ID   ADL00034 standard; protein; 554 AA.
AC   ADL00034;
DT   15-JUN-2007  (revised)
DT   20-MAY-2004  (first entry)
DE   Streptococcus agalactiae ORF SAG0645-related protein 1.
KW   immunogenic composition; group B Streptococcus; GBS; antibacterial;
KW   streptococcal infection; vaccine; SAG; BOND_PC;
KW   cell wall surface anchor family protein; hypothetical protein;
KW   hypothetical protein gbs0628 [Streptococcus agalactiae NEM316];
KW   Unknown [Streptococcus agalactiae NEM316]; GO9986.
OS   Streptococcus agalactiae 2603V/R.
PN   WO2004018646-A2.
PD   04-MAR-2004.
PF   26-AUG-2003; 2003WO-US026827.
PR   26-AUG-2002; 2002US-0406237P.
PR   27-AUG-2002; 2002US-0406676P.
PR   28-AUG-2002; 2002US-0406757P.
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PA (CHIR) CHIRON CORP.
PA (GENO-) INST GENOMIC RES.
PI Tettelin H, Masignani V;
DR WPI; 2004-248071/23.
DR PC:NCBI; gi22536814.
PT Immunogenic composition useful as a vaccine for treating or preventing
PT streptococcal infections, comprises group B Streptococcus polypeptides.
PS Claim 10; SEQ ID NO 8710; 1194pp; English.
CC The invention relates to a novel immunogenic composition comprising a
CC combination of 2-5 group B Streptococcus (GBS) polypeptides. Each
CC polypeptide is encoded by a GBS polynucleotide sequence which is
CC homologous to a polynucleotide sequence of group A Streptococcus (GAS),
CC Streptococcus pneumoniae and/or least one other GBS serotype. The
CC composition of the invention demonstrates antibacterial activity whilst
CC the polypeptides and polynucleotides may be useful in assays to diagnose
CC and identify streptococcal infections or for identifying, screening and
CC developing vaccines and other treatments for streptococcal infections.
CC The current sequence is that of a Streptococcus agalactiae ORF SAG
CC protein of the invention.
CC Revised record issued on 15-JUN-2007 : Enhanced with precomputed
CC information from BOND.
SQ Sequence 554 AA;

Query Match 100.0%; Score 2642; DB 1; Length 554;
Best Local Similarity 100.0%;
Matches 517; Conservative 0; Mismatches 0; Indels 0; Gaps 0.

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Qy          1 AEVSQERPAKTTVNIYKLQADSYKSEITSNGGIENKDGEVISNYAKLGDNVKGLQGVQFK 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         38 AEVSQERPAKTTVNIYKLQADSYKSEITSNGGIENKDGEVISNYAKLGDNVKGLQGVQFK 97

Qy         61 RYKVKTDISVDELKKLTTVEAADAKVGTILEEGVSLPQKTNAQGLVVDALDSKSNVRYLY 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         98 RYKVKTDISVDELKKLTTVEAADAKVGTILEEGVSLPQKTNAQGLVVDALDSKSNVRYLY 157

Qy        121 VEDLKNSPSNITKAYAVPFVLELPVANSTGTGFLSEINIYPKNVVTDEPKTDKDVKKLGQ 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        158 VEDLKNSPSNITKAYAVPFVLELPVANSTGTGFLSEINIYPKNVVTDEPKTDKDVKKLGQ 217

Qy        181 DDAGYTIGEEFKWFLKSTIPANLGDYEKFEITDKFADGLTYKSVGKIKIGSKTLNRDEHY 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        218 DDAGYTIGEEFKWFLKSTIPANLGDYEKFEITDKFADGLTYKSVGKIKIGSKTLNRDEHY 277

Qy        241 TIDEPTVDNQNTLKITFKPEKFKEIAELLKGMTLVKNQDALDKATANTDDAAFLEIPVAS 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        278 TIDEPTVDNQNTLKITFKPEKFKEIAELLKGMTLVKNQDALDKATANTDDAAFLEIPVAS 337

Qy        301 TINEKAVLGKAIENTFELQYDHTPDKADNPKPSNPPRKPEVHTGGKRFVKKDSTETQTLG 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        338 TINEKAVLGKAIENTFELQYDHTPDKADNPKPSNPPRKPEVHTGGKRFVKKDSTETQTLG 397

Qy        361 GAEFDLLASDGTAVKWTDALIKANTNKNYIAGEAVTGQPIKLKSHTDGTFEIKGLAYAVD 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        398 GAEFDLLASDGTAVKWTDALIKANTNKNYIAGEAVTGQPIKLKSHTDGTFEIKGLAYAVD 457

Qy        421 ANAEGTAVTYKLKETKAPEGYVIPDKEIEFTVSQTSYNTKPTDITVDSADATPDTIKNNK 480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        458 ANAEGTAVTYKLKETKAPEGYVIPDKEIEFTVSQTSYNTKPTDITVDSADATPDTIKNNK 517
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Qy        481 RPSIPNTGGIGTAIFVAIGAAVMAFAVKGMKRRTKDN 517
              |||||||||||||||||||||||||||||||||||||
Db        518 RPSIPNTGGIGTAIFVAIGAAVMAFAVKGMKRRTKDN 554
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SEQ ID NO: 38

```
ADK99683
ID   ADK99683 standard; protein; 417 AA.
AC   ADK99683;
DT   20-MAY-2004  (first entry)
DE   Streptococcus agalactiae ORF SAG0032-related protein 11.
KW   immunogenic composition; group B Streptococcus; GBS; antibacterial;
KW   streptococcal infection; vaccine; SAG.
OS   Streptococcus agalactiae.
PN   WO2004018646-A2.
PD   04-MAR-2004.
PF   26-AUG-2003; 2003WO-US026827.
PR   26-AUG-2002; 2002US-0406237P.
PR   27-AUG-2002; 2002US-0406676P.
PR   28-AUG-2002; 2002US-0406757P.
PA   (CHIR ) CHIRON CORP.
PA   (GENO-) INST GENOMIC RES.
PI   Tettelin H,  Masignani V;
DR   WPI; 2004-248071/23.
PT   Immunogenic composition useful as a vaccine for treating or preventing
PT   streptococcal infections, comprises group B Streptococcus polypeptides.
PS   Claim 10; SEQ ID NO 6922; 1194pp; English.
CC   The invention relates to a novel immunogenic composition comprising a
CC   combination of 2-5 group B Streptococcus (GBS) polypeptides. Each
CC   polypeptide is encoded by a GBS polynucleotide sequence which is
CC   homologous to a polynucleotide sequence of group A Streptococcus (GAS),
CC   Streptococcus pneumoniae and/or least one other GBS serotype. The
CC   composition of the invention demonstrates antibacterial activity whilst
CC   the polypeptides and polynucleotides may be useful in assays to diagnose
CC   and identify streptococcal infections or for identifying, screening and
CC   developing vaccines and other treatments for streptococcal infections.
CC   The current sequence is that of a Streptococcus agalactiae ORF SAG
CC   protein of the invention.
SQ   Sequence 417 AA;

  Query Match             100.0%;  Score 1968;  DB 1;  Length 417;
  Best Local Similarity   100.0%;
  Matches  392;  Conservative  0;  Mismatches   0;  Indels  0;  Gaps  0.

Qy          1 DLVKQDNKSSYTVKYGDTLSVISEAMSIDMNVLAKINNIADINLIYPETTLTVTYDQKSH 60
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 DLVKQDNKSSYTVKYGDTLSVISEAMSIDMNVLAKINNIADINLIYPETTLTVTYDQKSH 60

Qy         61 TATSMKIETPATNAAGQTTATVDLKTNQVSVADQKVSLNTISEGMTPEAATTIVSPMKTY 120
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 TATSMKIETPATNAAGQTTATVDLKTNQVSVADQKVSLNTISEGMTPEAATTIVSPMKTY 120

Qy        121 SSAPALKSKEVLAQEQAVSQAAANEQVSPAPVKSITSEVPAAKEEVKPTQTSVSQSTTVS 180
              |||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 SSAPALKSKEVLAQEQAVSQAAANEQVSPAPVKSITSEVPAAKEEVKPTQTSVSQSTTVS 180
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Qy        181 PASVAAETPAPVAKVAPVRTVAAPRVASVKVVTPKVETGASPEHVSAPAVPVTTTSPATD 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 PASVAAETPAPVAKVAPVRTVAAPRVASVKVVTPKVETGASPEHVSAPAVPVTTTSPATD 240

Qy        241 SKLQATEVKSVPVAQKAPTATPVAQPASTTNAVAAHPENAGLQPHVAAYKEKVASTYGVN 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 SKLQATEVKSVPVAQKAPTATPVAQPASTTNAVAAHPENAGLQPHVAAYKEKVASTYGVN 300

Qy        301 EFSTYRAGDPGDHGKGLAVDFIVGTNQALGNKVAQYSTQNMAANNISYVIWQQKFYSNTN 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 EFSTYRAGDPGDHGKGLAVDFIVGTNQALGNKVAQYSTQNMAANNISYVIWQQKFYSNTN 360

Qy        361 SIYGPANTWNAMPDRGGVTANHYDHVHVSFNK 392
              ||||||||||||||||||||||||||||||||
Db        361 SIYGPANTWNAMPDRGGVTANHYDHVHVSFNK 392
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SEQ ID NO: 7

```
ADL00034
ID   ADL00034 standard; protein; 554 AA.
AC   ADL00034;
DT   15-JUN-2007  (revised)
DT   20-MAY-2004  (first entry)
DE   Streptococcus agalactiae ORF SAG0645-related protein 1.
KW   immunogenic composition; group B Streptococcus; GBS; antibacterial;
KW   streptococcal infection; vaccine; SAG; BOND_PC;
KW   cell wall surface anchor family protein; hypothetical protein;
KW   hypothetical protein gbs0628 [Streptococcus agalactiae NEM316]; Unknown;
KW   Unknown [Streptococcus agalactiae NEM316]; GO9986.
OS   Streptococcus agalactiae 2603V/R.
PN   WO2004018646-A2.
PD   04-MAR-2004.
PF   26-AUG-2003; 2003WO-US026827.
PR   26-AUG-2002; 2002US-0406237P.
PR   27-AUG-2002; 2002US-0406676P.
PR   28-AUG-2002; 2002US-0406757P.
PA   (CHIR ) CHIRON CORP.
PA   (GENO-) INST GENOMIC RES.
PI   Tettelin H,  Masignani V;
DR   WPI; 2004-248071/23.
DR   PC:NCBI; gi22536814.
PT   Immunogenic composition useful as a vaccine for treating or preventing
PT   streptococcal infections, comprises group B Streptococcus polypeptides.
PS   Claim 10; SEQ ID NO 8710; 1194pp; English.
CC   The invention relates to a novel immunogenic composition comprising a
CC   combination of 2-5 group B Streptococcus (GBS) polypeptides. Each
CC   polypeptide is encoded by a GBS polynucleotide sequence which is
CC   homologous to a polynucleotide sequence of group A Streptococcus (GAS),
CC   Streptococcus pneumoniae and/or least one other GBS serotype. The
CC   composition of the invention demonstrates antibacterial activity whilst
CC   the polypeptides and polynucleotides may be useful in assays to diagnose
CC   and identify streptococcal infections or for identifying, screening and
CC   developing vaccines and other treatments for streptococcal infections.
CC   The current sequence is that of a Streptococcus agalactiae ORF SAG
CC   protein of the invention.
```

```
CC   Revised record issued on 15-JUN-2007 : Enhanced with precomputed
CC   information from BOND.
SQ   Sequence 554 AA;

  Query Match             100.0%;  Score 2473;  DB 1;  Length 554;
  Best Local Similarity   100.0%;
  Matches  483;  Conservative  0;  Mismatches  0;  Indels  0;  Gaps  0.

Qy          1 AEVSQERPAKTTVNIYKLQADSYKSEITSNGGIENKDGEVISNYAKLGDNVKGLQGVQFK 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         38 AEVSQERPAKTTVNIYKLQADSYKSEITSNGGIENKDGEVISNYAKLGDNVKGLQGVQFK 97

Qy         61 RYKVKTDISVDELKKLTTVEAADAKVGTILEEGVSLPQKTNAQGLVVDALDSKSNVRYLY 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         98 RYKVKTDISVDELKKLTTVEAADAKVGTILEEGVSLPQKTNAQGLVVDALDSKSNVRYLY 157

Qy        121 VEDLKNSPSNITKAYAVPFVLELPVANSTGTGFLSEINIYPKNVVTDEPKTDKDVKKLGQ 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        158 VEDLKNSPSNITKAYAVPFVLELPVANSTGTGFLSEINIYPKNVVTDEPKTDKDVKKLGQ 217

Qy        181 DDAGYTIGEEFKWFLKSTIPANLGDYEKFEITDKFADGLTYKSVGKIKIGSKTLNRDEHY 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        218 DDAGYTIGEEFKWFLKSTIPANLGDYEKFEITDKFADGLTYKSVGKIKIGSKTLNRDEHY 277

Qy        241 TIDEPTVDNQNTLKITFKPEKFKEIAELLKGMTLVKNQDALDKATANTDDAAFLEIPVAS 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        278 TIDEPTVDNQNTLKITFKPEKFKEIAELLKGMTLVKNQDALDKATANTDDAAFLEIPVAS 337

Qy        301 TINEKAVLGKAIENTFELQYDHTPDKADNPKPSNPPRKPEVHTGGKRFVKKDSTETQTLG 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        338 TINEKAVLGKAIENTFELQYDHTPDKADNPKPSNPPRKPEVHTGGKRFVKKDSTETQTLG 397

Qy        361 GAEFDLLASDGTAVKWTDALIKANTNKNYIAGEAVTGQPIKLKSHTDGTFEIKGLAYAVD 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        398 GAEFDLLASDGTAVKWTDALIKANTNKNYIAGEAVTGQPIKLKSHTDGTFEIKGLAYAVD 457

Qy        421 ANAEGTAVTYKLKETKAPEGYVIPDKEIEFTVSQTSYNTKPTDITVDSADATPDTIKNNK 480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        458 ANAEGTAVTYKLKETKAPEGYVIPDKEIEFTVSQTSYNTKPTDITVDSADATPDTIKNNK 517

Qy        481 RPS 483
                |||
Db         518 RPS 520
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Since the prior art GBS polypeptides or fragments are identical in structure or amino acid composition with the instantly recited polypeptides or fragments, they are expected to necessarily possess the same identical function(s) recited in the instant claims, i.e., improved immunogenicity as measured by the Active Maternal Immunization Assay and higher percent survival rate in challenged pups from female mice immunized with a single non-GBS 80 antigen. The functions recited by Applicants are viewed as inherent properties inseparable from the prior art products. Products identical in structure cannot have mutually exclusive properties.

Claims 1-4, 8-10, 14-17 and 27-30 are anticipated by Tettelin *et al.*

Claim(s) Objection(s)

14) Claims 1, 8, 10, 14-17 and 27-30 are objected to for not leaving a space after the limitation 'NO:'.

Remarks

15) Claims 1-4, 8-10, 14-17 and 27-30 stand rejected.

16) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax number (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

17) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

18) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

November, 2009